RESPONSES TO PUBLIC COMMENTS SUBMITTED REGARDING THE MAY 8, 1998 FEDERAL REGISTER NOTICE (64 FR 2635) OF EPA'S INTENT TO PROPOSE REMOVING REQUIRED USES OF SW-846 METHODS FROM THE RCRA REGULATIONS

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Introduction

On May 8, 1998 (63 FR 25430), the U.S. Environmental Protection Agency (the Agency or EPA) published a notice of intent to reform the implementation of RCRA-related methods and monitoring. One reform measure included removing unnecessary required uses of SW-846 methods from the RCRA regulations. The Agency posed four specific questions to the public regarding this topic. This document summarizes the public comments on each of the four questions and provides the Agency's responses. This response to comment document was developed for inclusion in the docket to the proposed rule to remove unnecessary required uses of SW-846 methods (Methods Innovation Rule or MIR). Any mention of a proposed rule in the comment responses refers to the MIR.

I. *Are Any of the Required Uses of SW-846 Methods in the RCRA Regulations for Other than Method-defined Parameters Necessary?*

1. Comment: One commenter (Washington State Dept. of Ecology) believed that some regulations should include testing requirements and indicate which testing method is appropriate. The commenter gave the following regulations as examples: 40 CFR 261.21(a)(2), characteristic of ignitable solids; 40 CFR 261.23, characteristic of reactivity; 40 CFR 261.3(a)(2)(v), rebuttable presumption for used oil; and Appendix III to Part 261. The commenter also stated that his State government needs assurance that EPA will dedicate personnel to provide training and guidance documents regarding which methods will satisfy regulatory requirements.

Response: The Agency does not agree with the commenter's examples of regulations that should include method-specific testing requirements. The 40 CFR 261.21(a)(2) (characteristic for ignitable solids) and 40 CFR 262.23 (reactivity characteristic) regulations currently do not mention any specific methods and a demonstration of whether a waste exhibits these hazardous waste characteristics instead relies on generator knowledge. The Agency believes that there are no test methods capable of accurately identifying those characteristics in a waste. If such methods existed, EPA would revise the regulations to require use of the methods, since they would be used to analyze a method-defined parameter. Regarding the third example, 40 CFR 261.3(a)(2)(v), the MIR proposed rule is revising this used oil rebuttable presumption regulation to clarify that appropriate methods other than SW-846 methods are options for the demonstration. EPA does not believe it is necessary to require specific methods because this demonstration could be made for many different types of wastes or analytes and is not dependent on any particular method technology to generate a correct answer. Regarding the last example, Appendix III to Part 261, "Chemical Analysis Test Methods," purposely does not include testing requirements. Its role is only to refer readers to Chapter Two of SW-846 for guidance on method selection.

Regarding the need for training of regulatory personnel, the Agency will offer guidance to the States, EPA Regions and the regulated community regarding the implementation of this rule by means of training modules, workshops, and fact sheets. The Agency has already developed and presented at many different national locations a relevant training module entitled "Analytical Strategy for the RCRA Program." The Agency is currently developing another module to assist regulated entities and others in the determination of applicable methods. EPA is also developing checklists and other tools that may be used to document appropriate method performance.

2. Comment: One commenter (California Dept. of Toxic Substances Control) agreed that EPA should limit required uses of SW-846 methods to method-defined parameters. The commenter added that EPA should provide a list of these methods for public comment. The commenter believed that Method 3050 is used for a method-defined parameter, and that this method should be included in the aforementioned list. The Agency should continue to require SW-846 methods for all other uses, but allow a PBMS approach in specific instances upon approval of the regulating agency.

Response: The Agency agrees that any required uses of SW-846 methods should be restricted to method-defined parameters. The MIR proposed rule lists those SW-846 methods that will remain incorporated by reference in the RCRA regulations at 40 CFR 260.11(a). The public can

comment on the list. The list does not include Method 3050, "Acid Digestion of Sediments, Sludges, and Soils," because it is a preparatory method that is not required by RCRA regulation for analysis of a method-defined parameter.

The Agency disagrees that a PBMS approach should only be allowed on an individual basis if approved by the regulatory agency. EPA currently allows a PBMS approach throughout many of its RCRA regulations and does not normally require approval or advanced notification to use it. Such an approach would be counter to the purpose of adopting PBMS. When regulated entities decide to use a PBMS approach, EPA does recommend that they consult with their regulating authorities (State or Federal) during development of performance goals and during method selection.

3. Comment: One commenter (Laidlaw Environmental Services) noted that additional methods "should be required." The commenter listed Method 1312 "Synthetic Precipitation Leaching Procedure," Method 1320 "Multiple Extraction Procedure," and Method 5035, "Closed System Purge-and-Trap and Extraction for Volatile Organics in Soil and Waste Samples."

The commenter also noted that "holding times for analytical parameters specified in SW-846 must remain defined." However, the commenter stated that many of the currently defined holding times have no technical basis and review and revision is very much needed.

Response: The methods listed by the commenter are not required by any RCRA regulation and EPA does not plan to add regulations which require those methods. There is no regulatory reason to do so at this time. Two of them (Methods 1312 and 1320) are used in the analysis of method-defined parameters. (A method may exist for the analysis of an MDP and still not be part of a regulation.) Method 5035 is not used in the analysis of a method-defined parameter.

Regarding holding times specified in SW-846, the Agency believes that this issue is outside the scope of the present proposed rule. However, the Agency is developing new guidance on holding times for volatile compounds. The appropriate SW-846 methods will be revised as necessary to reflect that guidance once it is issued. Alternate holding times to those published may be employed provided that the generator or analyst can demonstrate appropriate analyte stability.

4. Comment: One commenter (ACIL Environmental Sciences Section) agreed that there are no necessary required uses of SW-846 for other than method-defined parameters. The commenter supported removal of SW-846 "incorporation by reference" in 40 CFR 260.11, and any other specific mention of the manual in the RCRA regulations, except for method-defined parameters. In addition, the commenter believed that EPA should provide guidance on which SW-846 methods are appropriate for given monitoring applications (e.g., similar to the list of recommended methods in Part 264 for Appendix IX groundwater monitoring). However, this guidance should clearly indicate that other options are possible under a PBMS approach.

Response: A complete list of appropriate or recommended methods for all RCRA monitoring requirements is not practical. Whether any method is appropriate for any given monitoring situation is a project- and matrix-specific issue. It was relatively easy to provide examples in Appendix IX to Part 264 for a matrix such as groundwater. However, any list of example appropriate methods, including the one in Part 264 for groundwater monitoring, becomes quickly outdated due to the many and frequent advances in method development. (It is for this

reason that the Agency is proposing to remove the SW-846 methods listed in Appendix IX to Part 264.) Given this environment and the Agency's plan to promote a PBMS approach, it is not likely that the Agency will publish any more similar lists in the regulations. In addition, developing a list of SW-846 methods to cover most circumstances would be very difficult, and may discourage the consideration of other methods from other sources. Instead, EPA recommends that regulated entities consult with their regulating authorities for guidance during method selection. In addition, the Agency does not plan on issuing lists of "recommended" methods, because "recommended" is too easily misconstrued to be "required" and thus defeats the purpose of this rulemaking and goes counter to EPA's policy on PBMS.

5. Comment: Two commenters (Chemical Manufacturer's Association and Ford Motor Company) requested clarification regarding the term "method-defined" parameter and more method examples. In addition, one commenter (Ford Motor Company) believed that all parameters are "method-defined" because any change made to a method will have an impact on the end result with a strong dependence on the matrix. The commenter cited the following example actions as capable of altering results: altering the pH, solvent, reagents, extraction time or conditions in a preparation step; the manner in which the reagents, glassware and equipment are prepared, calibrated and maintained; changing the chromatographic or chemical separation technique; and altering the use of the determinative step (e.g., Office of Water's Streamlining Proposal).

Response: In the proposed rule, the Agency clarifies the term "method-defined parameter (MDP)" and provides several examples of methods used for such a parameter. An MDP is a measurable property where the analytical result is wholly dependant on the process or technology used to make the measurement. The property can be correctly measured by only one particular method. Some method-defined properties are not required analyses in the RCRA regulations and some are. Examples of RCRA-required method-defined parameters and their SW-846 methods include Method 1311, "The Toxicity Characteristic Leaching Procedure" (TCLP), used to determine whether waste leaching potential is greater than the levels specified in the toxicity characteristic at 40 CFR 261.24; Method 9040, "pH Electrometric Measurement," used to demonstrate whether a waste exhibits the corrosivity characteristic based on pH levels; and Method 9095, "Paint Filter Liquids Test," used to demonstrate the absence or presence of free liquids in wastes managed in RCRA-regulated treatment, storage, and disposal facilities.

Some of the method changes mentioned by one of the commenters might affect a result. However, such changes are part of the process to optimize a particular method to maximize analytical performance, e.g., recovery of the analytes of concern from a given matrix, and should not be confused with method use to analyze a method-defined parameter as defined by this proposed action.

Also, for the purposes of this rulemaking, whether or not any method change would change a result is not what defines an MDP. What defines an MDP method, in the context of this rule, is whether it is, as written, used to define a regulatory parameter. Sometimes the "parameter" cited by the regulation was developed in conjunction with the method. For example, the TCLP test is used to determine if a waste exhibits the characteristic of toxicity. The TCLP was the test used to develop the particular leachate of concern (a waste extract) and the regulatory thresholds specified in the regulations. The TCLP was developed to emulate the leachate that might be generated if the waste was co-disposed. No other method is known to yield the same leachate from a waste as the TCLP. Also, the TCLP is used only to generate the leachate itself,

and is not used to specifically determine the analyte levels in the leachate. Any reliable and appropriate method can be used to determine the total constituent levels in a TCLP leachate. The determinative measurement of the leachate itself does not involve measurement of an MDP.

The Agency also notes that adoption of a PBMS approach does not mean that any change to a method should be made. As noted above, method modifications are primarily done to improve characterization performance for certain analytes in a given sample matrix. Obviously, method changes should be avoided if they will adversely affect its ability to accurately characterize the analytes of concern in the matrix of concern and if performance objectives cannot be met. Performance factors of concern might include precision, accuracy (or bias), recovery, representativeness, comparability, and sensitivity (detection, quantitation, or reporting limits). Regulated entities should demonstrate and document that any procedure, even an unchanged method, is capable of providing appropriate performance for its intended application.

6. Comment: One commenter (American Petroleum Institute) said that EPA should provide more specific information as to its plans for revising the regulations to remove SW-846 requirements. The FR notice merely stated that EPA may "remove" required uses of SW-846 except where SW-846 defines the regulatory parameters. The commenter added that this explanation does not identify specifically which rules the EPA believes require use of SW-846, or which of those rules use SW-846 to define parameters. The commenter provided a listing of regulations that specify the use of SW-846.

Response: The Agency provides specific information in the MIR proposed rule on how the regulations will be revised to remove unnecessary required uses of SW-846 methods. With the exception of 40 CFR 261.24 (toxicity characteristic), all the regulatory references listed by the commenter are proposed for revision by the MIR rule. The Agency believes that these required uses of SW-846 methods are unnecessary and should be removed from the RCRA regulations. The Agency intends to restrict the required uses of SW-846 to only those cases where the SW-846 method defines the regulatory parameter. Such is the case of 40 CFR 261.24, the toxicity characteristic, which specifies the use of SW-846 Method 1311, "The Toxicity Characteristic Leaching Procedure" (TCLP).

II. *What Might Be the Economic Impact on the Regulated Community and Other Entities (e.g., Small Businesses) as a Direct Result of the Removal of Certain Required Uses of SW-846 Methods?*

1. Comment: One commenter (Washington State Dept. of Ecology) believed that the immediate impact on the regulated community may be a feeling of uncertainty as a result of the removal of certain required uses of SW-846 methods. Members of the regulated community may wonder if they have spent their money to use a correct test method. Regulating agencies may experience a degree of uncertainty as well. The commenter also anticipated cost increases to State governments that are associated with training regulatory staff, such as compliance personnel, to evaluate analytical results.

Another commenter (EDF) stated that, given limited program resources at the State and Federal levels, it may not be either feasible or appropriate to devote substantial program resources toward the review of new and unproven testing methods selected by various members of the regulated community. At a minimum, EPA must carefully evaluate each proposed rule change in this regard.

Response: The Agency believes that communication and training, at all levels, will help address any concerns that the regulated community and regulatory agencies may have regarding implementation of the proposed revisions. The Agency plans to provide guidance to all parties through training modules, workshops and other outreach activities. The Agency believes that such communication and training efforts will help ensure consistency in implementation of this rule and help limit any associated costs. Each data generating effort is project-specific and has different analytical needs, and this approach to monitoring is more adaptable to those differences. The Agency recommends that members of the regulated community work with the regulating authorities during development of performance criteria and method selection. This approach in particular should help diminish uncertainty within the regulated community. A strong EPA Headquarters leadership will be present to enable implementation of this approach to RCRA-related monitoring. The Agency does not believe that the proposed revisions will result in significant cost increases to State governments for training staff on how to evaluate data. Under RCRA, regardless of the method used, the States should already be conducting reviews of analytical results. If States and regulated entities are not currently evaluating the data against project DQOs and other project-specific requirements, then they are not adequately documenting the effectiveness of the data and the correctness of related decisions.

Finally, as noted in the proposed rule, we specify that only appropriate methods should be used in lieu of the required SW-846 methods (e.g., and thus not just any new method), and that such methods should be published by reliable sources and accepted as such by the scientific community. This process for method selection is no different then that generally practiced during compliance with existing regulations which do not explicitly require a particular method.

2. Comment: One commenter (Chemical Manufacturer's Association) believed that functioning under PBMS as a result of the removal of certain required uses of SW-846 methods could have a favorable economic impact if certain controls are put into place to limit costs connected to demonstrating and documenting method performance.

Response: Although the commenter did not provide specific examples of method performance cost controls, the Agency generally disagrees that controls in demonstrating method performance should be put in place to limit costs. The Agency believes that QC measures or other activities to demonstrate adequate method performance should be identified during the planning stage. The types and numbers of such measures are project-specific considerations and should not be controlled in general terms. EPA expects project planners to try to control costs through all stages of the project, to the degree possible without sacrificing effective data. In addition, the Agency believes that demonstrating that a method other than SW-846 is appropriate should not involve much more than what already is done for any sampling and analysis effort under RCRA, e.g., when showing that SW-846 methods are appropriate for a given analyte and matrix. The proposed action does not add any new regulatory requirements or require any additional reports beyond those already required.

3. Comment: Two commenters (ACIL Environmental Sciences Section and American Petroleum Institute) believed that the regulated community should benefit from cost effective monitoring programs as a result of the removal of certain required uses of SW-846 methods. However, both commenters stated that there will be little economic benefit to the regulated community if EPA/OSW-HQ and EPA/ORD do not provide effective guidance and support to the EPA Regions and States. Another commenter believed that there will be no beneficial impact on the regulated, unless and until authorized States incorporate the changes. The commenter was confident that, if guidance is provided, the States will implement the changes and allow use of the PBMS approach, in lieu of strict use of SW-846 methods.

Response: The Agency agrees with the commenters that the regulated community stands to benefit from the use of cost-effective monitoring technologies once the unnecessary required uses of SW-846 methods are eliminated. The Agency believes that additional flexibility in method use, as provided by the proposed revisions, will provide opportunities for cost savings in RCRA-relating sampling and analysis efforts. Appropriate project planning leading to proper cost-effective method selection will have a significant effect on reduction of analytical costs, an option which is currently available under the many existing regulations which do not unnecessarily require specific methods.

Adoption of the proposed revisions by authorized States is one key factor for successful nation-wide implementation of this rule. State participation will help ensure that all members of the regulated community fully benefit from the new flexibility allowed as a result of removing unnecessary requirements to use SW-846 methods. However, authorized States are not required to adopt the regulatory revisions.

The Agency also agrees that training of all parties involved -- the States, EPA Regions, and the regulated community -- is important to successful implementation of this rule. The Agency plans to offer training at all levels in order to ensure that the proposed revisions are implemented in as consistent manner as possible (given the project-specific nature of the sampling and analysis efforts) and that any associated costs are kept to a minimum. The Agency plans to offer guidance regarding the implementation of this rule by means of training modules, workshops, fact sheets and other outreach activities. Over the past few years, the Agency has provided relevant program-specific training (e.g., "Analytical Strategy for the RCRA Program: A

Performance-Based Approach") for EPA Headquarters, Regional, and State personnel involved in RCRA activities that include sampling and analysis. The Agency also plans to offer other courses on the evaluation of data and permit writing from a PBMS and effective data standpoint.

4. Comment: One commenter (Ford Motor Company) noted that the impact on the regulated community and other entities is wholly dependent upon the Agency's PBMS implementation plan which has yet to be defined. The commenter stated that this could have a negative impact on independent testing laboratories. The impact on small businesses will be influenced by how much PBMS drives the cost of analysis up. Large corporations with their own analytical testing capabilities will likely save money in testing costs under PBMS. However, the compliance and enforcement issues could easily outweigh any benefits gained through the system.

Response: The commenter did not give specific examples of negative impacts and compliance issues that might outweigh any benefits, therefore, the Agency cannot fully respond to the comment. However, the Agency provides in the proposed rule some information on how it plans to implement a PBMS approach for RCRA-related sampling and analysis efforts. In addition, the OSW Methods Team web site provides information regarding the RCRA methods program approach to PBMS implementation. A copy of the OSW's PBMS implementation plan (which addresses PBMS implementation within the RCRA Program) can be found at http://www.epa.gov/epaoswer/hazwaste/test/pbms.htm.

The Agency expects that the proposed action to remove unnecessary required uses of SW-846, when finalized, will promote overall cost effectiveness and help reduce costs. The proposed action lifts restrictions to use methods other than SW-846, effectively increasing the choices of appropriate analytical methods available to the regulated community. Thus, regulated entities can select methods that are more appropriate and cost-effective for their particular applications.

The Agency also believes that demonstrating and documenting method performance under a PBMS approach generally should not entail additional costs. Demonstrating that a method is appropriate, whether it is an SW-846 method or another method, should not involve much more that what already should be done for any RCRA sampling and analysis effort.

As part of the proposed rule, the Agency is seeking more comments from the regulated community regarding any concerns related to implementation and compliance assessments. The public should provide specific examples or reasons for any concerns.

III. *What Concerns Exist Regarding Implementation and Enforcement of the Allowed Use of "Other Appropriate Methods" in lieu of a Specific SW-846 Method for RCRA-related Monitoring?*

1. Comment: Some commenters (Washington State Dept. of Ecology and Ford Motor Company) were concerned about inconsistent implementation from state to state. One commenter (Washington State Dept. of Ecology) believed that without clear guidance from the EPA, the use of "other appropriate methods," in lieu of a specific SW-846 method for RCRA-related monitoring, would leave room for differing interpretations among the States as to which analyses meet the regulatory intent. The commenter felt that this situation could cause a great deal of confusion and frustration in the regulated community. This problem could arise due to the shift in the onus of determining what test method would meet the regulatory intent. As individual State authorities become responsible for implementing RCRA regulations, selecting methods from SW-846, or some other source of analytical test methods such as ASTM, may result in a wide variance of acceptable methods between the States.

Another commenter (Ford Motor Company) noted that most of the authorized States will need to revise their programs to adopt equivalent requirements under State law. Otherwise, different methods may be acceptable for the same waste analysis in different states. The commenter stated that this situation is a result of the PBMS requirements being imposed pursuant to pre-HSWA authority.

Response: In the proposed rule, the Agency provides more guidance regarding what constitutes an appropriate method for a sampling and analysis activity under RCRA. In general, such a method is reliable and accepted as such by the scientific community and is applicable to its intended use – i.e., the method will generate effective data. It is not problematic that different methods can be used for the same analytical determination, provided that the correct answer is reached. Each method could be appropriate and meet the performance goals of the project. Therefore, different methods can be used by different States or other entities for related decision-making, provided that appropriate methods are used and project-specific performance objectives are met. Method selection and use decisions are project-specific, and should be, given the wide variety of matrices and analytes of concern under the RCRA regulations.

Second, there are no "PBMS requirements" which must be adopted by the States. While the Agency encourages the adoption of the PBMS approach, authorized States are not required to revise their regulations and programs to incorporate this flexibility in method selection and use. This is because the proposed rule regulatory changes do not impose additional requirements (in fact, they instead remove existing requirements) and do not broaden the scope of the RCRA regulations. The revisions will be applicable only in those States that do not have final authorization. Therefore, in authorized States, the changes will not be applicable until and unless the State revises its program to adopt the revisions.

Finally, the Agency believes that guidance or training of all parties involved is needed to assure successful implementation of the revisions proposed in this rule. The Agency will provide training to States, Regions and the regulated community in the form of training modules, workshops, fact sheets and other outreach efforts to ensure consistent implementation.

2. Comment: One commenter (California Dept. of Toxic Substances Control) noted that the term "other appropriate methods" needs to be defined in a way that is consistent with legal standards. The commenter offered the example of California standards which require that data be generated by techniques which are "generally accepted in the scientific community." The commenter suggested that in order to determine compliance with Federal law, the definition should be consistent with guidance created by the Supreme court in the Daubert vs. Merrill-Dow case.

Response: In the proposed rule, the Agency clarifies the term "other appropriate methods." In general, the Agency considers a method appropriate for sampling and analysis activities under RCRA if it is reliable and accepted as such by the scientific community and applicable to its intended use – i.e., the method will generate effective data. The Agency believes this description is consistent with the case cited by the commenter, which addresses the concept of acceptance in the scientific community.

3. Comment: A few commenters were concerned about the impact on regulatory and enforcement practices. One commenter (ACIL Environmental Sciences Section) noted that the use of "other appropriate methods" in lieu of a specific SW-846 method for RCRA-related monitoring will require more training and knowledge of regulatory personnel. This represents risk for regulatory agencies without apparent reward. The commenter also believed that discretionary enforcement policy will be an issue. The commenter stated that regulatory limits are enforced without real consideration of confidence limits and measurement variability. However, approaches such as the DQO process and PBMS require consideration of these factors.

Another commenter (American Petroleum Institute) stated that, a final concern with implementation of "other appropriate methods," in lieu of a specific SW-846 method, is the need to demonstrate that the method will meet the intended use. Also, regulatory personnel presently accept SW-846 because it is the "RCRA Methods Manual." Regulatory personnel not trained in chemistry are inclined to select SW-846 without further thought. The commenter noted, however, that PBMS for RCRA-related monitoring will require more training and knowledge on the part of regulatory personnel. PBMS may, in some cases, be perceived by regulatory personnel as entailing some burden without regulatory benefit.

Another commenter (EDF) stated that the PBMS approach presents potentially significant enforcement hurdles. This commenter was concerned about the removal of required uses of methods involved in self-implementing regulations, such as the land disposal treatment standards, whereby there is no opportunity prior to an enforcement action to review the validity of an alternative test method.

Response: The Agency will offer training to the States, Regions and the regulated community regarding implementation of this rule to ensure consistency and to minimize any associated implementation and enforcement costs. The Agency's goal is to make the RCRA Program more effective and efficient by focusing monitoring regulations on what is to be accomplished by the monitoring rather than by focusing on the technologies used for the measurements. Rewards will include the cost effectiveness and flexibility in employing analytical test methods for RCRA-related testing and in the use of new and innovative technologies.

The Agency disagrees with one of the commenters that RCRA enforcement personnel do not consider the performance or appropriateness of a method. Enforcement personnel should verify that the method used by the regulated entity is appropriate for its intended use. For example, today some of the regulations require SW-846 use in general. However, many methods in SW-846 may have the same target analyte and yet all are not appropriate for a given matrix and project-specific data quality objective. It is still the responsibility of the regulated entity to demonstrate that any method used for compliance purposes, whether it is an SW-846 method or not, meets the data quality requirements for its intended application. Therefore, both the regulated entity and the regulating authority must evaluate which method is most appropriate for a given analyte and waste matrix. Promulgation of the MIR will not change this approach.

Regarding the methods required as part of the self-implementing regulations of the land disposal treatment standards, EPA has carefully considered the impacts of each proposed revision to the regulations, and determined that the cyanide methods of concern to the commenter should remain as required methods.

4. Comment: One commenter (American Petroleum Institute) posed two questions to the Agency. First, "How does the EPA intend to revise rules which currently allow the use of generator process knowledge as an alternative to the required or permitted use of SW-846 methods?" Second, "How will EPA address past delisting petitions that have been granted based upon the continuing condition that testing be performed under SW-846?"

Response: Any allowance to use generator "process knowledge" will not be affected by the proposed revisions and, therefore, will remain in the regulations unchanged. Regarding past delisting petitions that require use of SW-846 methods, the Agency is proposing to remove required uses of SW-846 methods from all conditional delistings. This is consistent with the other proposed revisions to remove unnecessary required uses of SW-846. The public may comment on the proposed changes to each of the delistings.

5. Comment: Several commenters (American Petroleum Institute, Ford Motor Company and (Chemical Manufacturer's Association) were concerned about the issue of method primacy. One commenter (Ford Motor Company) stated that method primacy is the key concern that exists regarding implementation and enforcement of the allowed use of other appropriate methods in lieu of a specific SW-846 method for RCRA-related monitoring. The commenter asked:

- How will either the regulator or regulated entity know that results generated by a PBMS cannot be challenged?

- How will the regulated community know that the "other appropriate method" has been properly validated, documented and is in compliance when a sample is analyzed?

- When differing results are obtained using two approved performance-based methods, which result is correct and how is that determined?

- Will the regulator’s method always be given primacy over the regulated entity?

Another commenter (American Petroleum Institute) noted that a barrier to implementation might be the reluctance of members of the regulated community to use "other appropriate methods"

because test results generated by different methods performed by EPA or other regulatory agencies may be disputed.

Another commenter (Chemical Manufacturer's Association) noted that the system, if implemented, will not be viable unless the method chosen by the regulated entity is the exclusive means by which compliance is judged.

Response: Many concerns about method primacy disputes are not well founded. Also, the first commenter made several incorrect assumptions, such as the one that a regulator's method always would be given primacy and that PBMS results cannot be challenged.

Under RCRA, the regulated entity is responsible for making the correct regulatory decision based on analytical data or other means. Even using required SW-846 methods does not relieve them of this responsibility. The regulated entity establishes performance criteria and demonstrates the performance results to verify that a method is appropriate. Sometimes, more than one method will lead to the right compliance decision, which is not a surprise given the wide variety of method technologies and performance capabilities (more than one may meet or exceed project-specific performance criteria). Regulatory personnel in turn evaluate the completeness of the method performance demonstration to determine if the method used was appropriate and if the correct decision was made.

Therefore, under RCRA, making the correct regulatory decision is of primary importance, not how (e.g., method used) one gets to it. Even during the use of required methods, the performance data must be evaluated and compared with project performance objectives. A decision should not be made based on results assumed to be adequate just because one used the method that was required or mentioned by a particular regulation. The Agency hopes that information in the proposed rule and EPA-developed training and guidance will help all affected parties better understand these principles.

The Agency also believes that regulated entities should consult with their regulating authority during identification of performance goals and the selection of appropriate methods. Working closely with their regulating agency, they should identify potentially appropriate methods for a specific project before sampling and analysis begins. This is recommended even for required uses of SW-846. Regulated entities should include performance goals in the QAPP or SAP and evaluate how well the method meets them based on the results of the QC data or other performance indicators. If a method does not meet the criteria, another might be selected, again in consultation with the regulating authority.

The Agency acknowledges that an appropriate method may give different waste analysis results at different times and two appropriate methods may give different results, for various reasons. Also, any result can be "challenged," even one based on a required SW-846 method. For these and other reasons, the Agency believes that it is important that adequate performance data be generated. These data can then be used to settle any disputes that arise.

6. Comment: One commenter (American Petroleum Institute) believed that, for groundwater monitoring, the EPA should specify designated reference methods (DRMs), both for sample preparation and for instrumental analysis. DRMs should be used in resolving compliance issues. The commenter believed that DRMs would not preclude the use of PBMS, and could provide an agreed-upon baseline method for the purpose of dispute resolution. Another commenter

suggested that clearly defined standard reference or referee methods are needed in order to validate performance-based methods and settle disputes which may arise.

Response: The Agency disagrees that it should specify reference methods for ground water monitoring, or any other RCRA-related monitoring, for the purpose of resolving disputes regarding method results. This approach is not appropriate given that a wide variety of matrices and analytes of concern may be encountered by the regulated community under the RCRA Program, and any one reference method specified by the Agency may not be appropriate for all situations and thus would not work well for resolving all disputes.

Instead, the Agency currently recommends the use of reference materials or standards during demonstrations of a method's performance. Unfortunately, for the RCRA Program, such materials are not available in a wide enough variety of matrices and analytes to serve all program needs. Nevertheless, although reference materials may not be available for every analysis, QC checks such as matrix spikes, matrix spike duplicates and use of the method of standard additions can be used to accurately demonstrate method performance (precision and bias).

7. Comment: One commenter (Ford Motor Company) stated that some parts of the RCRA regulations allow both SW-846 methods and "alternate methods approved by the administrator." In most cases, few or no alternate methods have been approved by the administrator, which has restricted the regulated community to using the SW-846 methods.

Second, the commenter raised an issue regarding the impression that most laboratories and auditors simply interpret SW-846 word-by-word to be conservative due to discrepancies that exist between the editions. The commenter stated that, if the first or second editions of SW-846 are specified in a State rule or permit, flexibility may be denied. The commenter noted that the first and second editions of SW-846 gave no indication that they were only intended to be used as guidelines. However, the third edition of SW-846 indicates that the methods can be used with some flexibility.

Response: Regarding the commenter's complaint about method approval times, the proposed rule will solve such problems by allowing the use of alternative methods without a lengthy approval process. EPA disagrees with the commenter's second concern. Within the Federal regulations and those of any authorized States, only the Third Edition of SW-846 should be cited for the purposes of waste analysis under the RCRA Program. The Third Edition replaced previous editions in 1986. The Third Edition and its first update were promulgated in 1993.

IV. *What Concerns Exist Regarding the Impact on State RCRA Programs of the Removal of Certain Required Uses of SW-846 Methods from the Federal RCRA Regulations?*

1. Comment: One commenter (Eastman Chemical Company) expressed concerns that States will not adopt PBMS and will continue to require specified methods.

Response: It is true that authorized States are not required to change their regulations and programs based on this proposed rule. Thus, States may continue to require specific SW-846 methods in their regulations for other than method-defined parameters. The Agency will recommend that States adopt the revisions proposed as part of this rule and will provide guidance regarding implementation of the Federal changes. EPA hopes that such guidance will mitigate some State concerns regarding adoption of a PBMS approach in their hazardous waste regulations.

2. Comment: One commenter (Washington State Dept. of Ecology) noted that States will need to create a training program for development of analytical methods that comply with the regulations. In addition, training will have to be provided to acquaint regulatory staff with appropriate new methods. Another commenter (Chemical Manufacturer's Association) stated that States will need technical assistance and training.

Response: EPA is providing and will continue to provide training to the States and other regulating entities (e.g., EPA Regions) on the principals of this rule, through such mechanisms as training modules, workshops, and fact sheets. EPA currently provides program-specific training through the training module "Analytical Strategy for the RCRA Program: A Performance-Based Approach" for EPA Headquarters, Regional, and State personnel. EPA plans to offer other courses on the evaluation of data and permit writing from a PBMS and effective data standpoint. Through this training effort, the Agency hopes to ensure consistency in implementation of this rule by the States, Regions, and regulated community and help limit any associated costs.

The proposed revisions will not require that States institute a training program on development of analytical methods, although they can do so if they wish. In addition, new method development will not always be necessary, given the many potentially appropriate methods that exist in SW-846 and other scientifically-accepted sources. The users of the methods will just have to continue to demonstrate that any method used is appropriate based on performance data, which is not different from what is currently done.

3. Comment: One commenter (California Dept. of Toxic Substances Control) believed that difficulties in enforcement and compliance as well as delays in issuance of permits will be the main impact on state RCRA programs. The commenter recommended that authorized State agencies maintain the required uses of SW-846 for all analyses, but be given the discretion of allowing an alternative performance-based method measurement system in lieu of SW-846. The commenter believed that in this way, the EPA could make suggested changes to SW-846 available to the regulated community and authorized agencies would have the discretion of allowing these changes to be implemented. Furthermore, the EPA could periodically update SW-846 by rulemaking, but, in the meantime, a mechanism would be in place to allow more flexibility and innovative technologies.

Response: First, authorized States will not be required to adopt the Federal changes and remove required uses of SW-846 from their regulations, although EPA encourages them to do so. In addition, the commenter's suggested approach is not logical and would be very difficult to legally implement and enforce. States could not both keep required uses of specific methods in their regulations and also allow the flexibility to use other methods -- it has to be one or the other. A method can be either required or not required -- not both. States may adopt the Federal agency's approach of mentioning a specific SW-846 method as an example of a potentially appropriate method.

Regarding the updating of SW-846, the Agency wishes to avoid the rulemaking process for most future SW-846 updates. The rulemaking process is lengthy and delays the timely use of new and improved monitoring technologies in RCRA-related testing. Because of the required uses of SW-846, the Agency has to issue the updates as a proposed rule, request public comment, and then promulgate the update in a final rule. Removal of most required uses of SW-846 methods from the RCRA regulations will promote more efficient and timely releases of new and revised SW-846 methods. A rulemaking will be necessary only when revising SW-846 to add or change a method-defined parameter in the RCRA regulations (e.g., a revision to Method 1311, the TCLP).

4. Comment: One commenter (American Petroleum Institute) believed that there may be little incentive for States to use "other appropriate methods" and incur the costs of demonstrating equivalency and reconciling potential bias between methods. The commenter believed that the current lack of statistical understanding by regulatory agency personnel, engineering/project management firms, laboratories and the regulated community make the prescriptive approach appear less risky than a PBMS approach.

Response: The Agency agrees that States may be hesitant about adopting the new approach, but also believes that demonstrating that a method is appropriate for its intended use does not represent an additional burden to States, other regulators, or the regulated community. After all, currently under RCRA, regardless of the method used -- even if it is an explicitly required method -- regulated entities should be demonstrating that the method is appropriate for its intended use, e.g., that it can adequately quantitate the analytes of concern in the particular waste matrix. Following a so-called more "prescriptive" approach does not relieve the regulated community from such a demonstration. The States in turn should be evaluating the completeness of such a demonstration, regardless of which method is used, when determining compliance. Therefore, this rule does not directly or indirectly propose new information collection requirements that must be processed by a State.

The Agency will need more information on the concerns regarding method equivalency, reconciling bias, and statistical understanding before responding further to this kind of comment. There might be a number of different issues of concern to the commenter. For instance, regarding "bias between methods," it will not be necessary to show equivalency with a previously required method. The regulated entity needs to only show that a particular method is appropriate to its current use and meets project objectives.

5. Comment: One commenter (Ford Motor Company) noted that a determination must first be made on whether or not existing methods are able to meet project DQOs. The commenter pointed out that even now there are no methods available which can meet delisting requirements

when all Appendix VIII compounds must be determined. SW-846 methods are unable to meet QA/QC criteria in many complex waste matrices.

The commenter questioned whether the EPA will identify suitable alternate methods or performance-based methods which can meet the analysis requirement set forth under RCRA.

Response: In general, the proposed flexibility will help resolve problems regarding method availability by allowing selection from a larger universe of potentially applicable methods. Regarding delisting demonstrations, delisting petitioners usually do not have to analyze for every analyte in Appendix VIII. Petitioners need only address constituents of concern to their particular waste. If no method is available, then delisting petitioners can use other approaches to demonstrate that an Appendix VIII analyte would not be present at levels of concern, such as use of a mass balance demonstration. Also, the proposed action will help solve any problems with the scope of appropriate methods in SW-846 because it will allow the use of other methods from other sources. In addition, the flexibility inherent in proper use of SW-846 methods allows method modifications that could expand the scope of analytes and increase sensitivity.

The Agency will retain mention of SW-846 methods in some of the regulations as examples of possible appropriate methods for RCRA-related sampling and analysis.